Message Text

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ORIGIN COME-00

INFO OCT-01 EA-10 ISO-00 EB-08 STR-07 TRSE-00 CIAE-00
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TO AMEMBASSY TOKYO PRIORITY

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E.O. 11652: N/A

TAGS: BEXP, JA

SUBJECT: TRADE FACILITATION COMMITTEE -- ABBOTT LABS
(TFC CASE 4)

REF: (A) STATE 128606; (B) TOKYO 04018; (C) STATE 141138;
(D) STATE 142267; (E) TOKYO 11301

1. SUMMARY: USDOC HAS RECEIVED INFORMATION FROM USFDA
SUPPORTIVE TO ABBOTT LABS CASE. GOJ OFFICIALS IN MEETINGS
WITH USG OFFICIALS MADE SEVERAL STATEMENTS THAT APPEAR TO
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REFLECT CURRENT MHW THINKING ON RESPONSE TO THIS CASE.
INFORMATION SUPPLIED BY AUBOTT LABS IN RESPONSE TO THESE
STATEMENTS EFFECTIVELY REBUTS POINTS RAISED BY GOJ
OFFICIALS, AND STRENGTHENS USG BELIEF THAT FURTHER DELAY IN
RESOLVING THIS CASE NOT RPT NOT JUSTIFIED. IN VIEW OF HIGH
LEVEL USG INTEREST IN THIS CASE.
AN INFORMAL MEETING BETWEEN EMBASSY,
MHW AND ABBOTT REPS MIGHT ALSO BE USEFUL. END SUMMARY.

2. THE U.S. FOOD AND DRUG ADMINISTRATIO' (FDA) SUPPLIED

FOLLOWING INFORMATION IN RESPONSE TO USDOC REQUEST FOR COMMENTS ON GOJ RESPONSE TO ABBOTT LABS CASE (REF B):
(1) MINISTRY OF HEALTH AND WELFARE (MHW) ACCEPTA CE OF FDA

AND OTHER U.S. DATA WOULD REDUCE SIGNIFICANTLY, PERHAPS BY AS MUCH AS ONE-HALF, TIME REQUIRED TO APPROVE AUSRIA;
(2) RE GOJ RESPONSE THAT AUSRIA NOT SUFFICIENTLY SENSITIVE IN DETECTING JAPANESE SUBTYPE OF HEPATITIS B ANTIGEN USFDA STATED: (BEGIN QUOTE) HEPATITIS B ANTIGEN SUBTYPES DO DIFFER BETWEEN U.S. AND JAPAN. SUBTYPE DIFFERENCES DESCRIBED, HOWEVER, SHOULD HAVE LITTLE INFLUENCE ON ABILITY OF A TEST TO DETECT THESE ANTIGENS SINCE THE MAJOR ANTIGENIC DETERMINANTS "A" AND "D" ARE THE SAME IN 0OTH COUNTRIES. THE OBJECTION PRESENTED IS A THEORETICAL ONE WHICH IN ALL PROBABILITY REPRESENTS A NON-PROBLEM. THE ABILITY OF ANY TEST TO DETECT THE HEPATITIS B ANTIGEN IS LARGELY DEPENDENT UPON ITS ABILITY TO DETECT THE GROUP ANTIGEN, "A" AND TO A LESSER EXTENT "D."

3. TO OUR KNOWLEDGE, GOJ HAS POLICY OF NOT ACCEPTING U.S.-GENERATED TEST DATA AS PART OF THE APPROVAL PROCESS FOR MEDICAL PRODUCTS. THE FDA, ON THE OTHER HAND, IS WILLING TO CONSIDER LEGITIMATE SOURCES OF TEST DATA
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REGARDLESS OF ORIGIN, PROVIDED THAT TEST SAMPLES FROM OVERSEAS CLINICAL EVALUATIONS ARE AVAILABLE FOR FURTHER TESTING, WHERE INDICATED, AT FDA. GOJ COULD MEET OUR REQUEST (REF A) THAT APPROVAL OF AUSRIA UNDER PHARMA-CEUTICAL AFFAIRS LAW (PAL) BE EXPEDITED BY AGREEING TO REVIEW FDA AND OTHER U.S. DATA.

4. IN MEETINGS IN WASHINGTON MAY 10 AND JUNE 1, MITI OFFICIALS HANAOKA AND HAYASHI INDICATED POTENTIAL GOJ POSITIONS WITH RESPECT TO THE ABBOTT CASE RESUBMISSION (REF A). HAYASHI MENTIONED THAT, ACCORDING TO RED CROSS OFFICIALS HE CONTACTED BEFORE LEAVING JAPAN, ABBOTT LABS HAD ALLEGEDLY NEVER APPROACHED THE JAPAN RED CROSS ON THE QUESTION OF PURCHASING AND USING AUSRIA. AS THIS FLATLY CONTRADICTED ABBOTT'S STATEMENTS, WE RECONTACTED ABBOTT SAME DAY FOR DETAILS OF ITS CONTACTS WITH RED CROSS. INFORMATION SUPPLIED BY ABBOTT DESCRIBES SERIES OF CONTACTS BETWEEN DAINABOT (ABBOTT JOINT VENTURE) AND RED CROSS OFFICIALS, INCLUDING EXTENSIVE RED CROSS TESTING OF AUSRIA TO COMPARE ITS EFFECTIVENESS WITH THE THEN-USED SECOND-GENERATION HEPATITIS TEST KNOWN AS CEP. ALL TESTS SHOWED AUSRIA MORE SENSITIVE THAN CEP. SOME OF THIS INFORMATION WAS GIVEN TO HAYASHI IN SECOND MEETING AT COMMERCE. THE FOLLOWING ARE PARAPHRASED EXCERPTS FROM DAINABOT TO ABBOTT TELEXES JUNE 6 AND 8 (FULL TEXT FORWARDED TO EMBASSY):

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A. THERE HAVE BEEN AT LEAST THREE INVESTIGATORS FROM JAPAN RED CROSS INVOLVED IN VARIOUS STUDIES ON AUSRIA.

THESE STUDIES WERE REPORTED AT 23RD GENERAL CONGRESS OF JAPAN SOCIETY OF BLOOD TRANSFUSION 1975.

(1) DR. TOKUNAGA (CENTRAL RED CROSS CENTER VICE PRES.) OF TOKYO RED CROSS STUDIED OVER 1400 SAMPLES, ALL OF WHICH WERE CEP NEGATIVE. USING AUSRIA HE FOUND AN ADDITIONAL
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1.2 PERCENT THAT WERE POSITIVE. STUDY DONE OCTOBER 1974 - FEBRUARY 1975.

(2) DR. ITO (HOKKAIDO RED CROSS) PUBLISHED STUDY IN AUGUST 1976 OF 1530 PATIENTS SHOWING AUSRIA MORE THAN TWICE AS SENSITIVE AS CEP.

(3) DR. HOSOI (KYOTO RED CROSS) COMPARED THE INCIDENCE OF POST TRANSFUSION HEPATITIS OVER A PERIOD OF TIME, ALSO CONFIRMING AUSRIA MORE SENSITIVE THAN CEP.

B. DAINABOT HAS HAD VARIETY OF CONTACTS WITH RED CROSS SINCE 1973 IN TRYING TO INFLUENCE THEM TO PURCHASE AUSRIA. IN JANUARY 1976, A SPECIFIC ACTION PROGRAM WAS DEVELOPED WITH THE RED CROSS TO HELP THEM PERSUADE MHW TO AUTHORIZE BUDGET FOR AUSRIA. ON FEBRUARY 15, 1976 RED CROSS TECH-NICAL COMMITTEE REACHED CONCLUSION THAT THIRD GENERATION RADIOIMMUNOASSAY (RIA) TEST WAS BEST METHODOLOGY BUT COULD NOT PERSUADE MHW TO ALLOCATE FUNDS. FEBRUARY 28, 1977 ABBOTT RECEIVED PHONE CALL FROM DR. TOKUNAGA REPORT-ING THAT MHW HAD INDICATED THE PURCHASE OF A COMMERCIAL TEST WAS TOO EXPENSIVE AND THAT RED CROSS WAS INSTRUCTED TO PRODUCE THEIR OWN THIRD GENERATION TEST.

C. JAPAN RED CROSS EXPERT GROUP VISITED ABBOTT AND U.S. RED CROSS FACILITIES MAY 5-15, 1974 TO STUDY AUSRIA. TEAM CONSISTED OF DR. EIICHI TOKUNAGA, DR. HIROTAKE KAKEHI (PROF. OF RADIOLOGY, CHIBA UNIVERSITY), DR. HIROS'I TOHYAMA (ASSISTANT PROF. OF TRA'SFUSION DIVISION, TOKYO UNIVERSITY) DR. FUMIHIRO IC;IDA (PROF. OF INTERNAL MEDICINE, NIIGATA UNIVERSITY), DR. YUICHI KUMAHARA (PROF. OF DIAGNOSTIC DIVISION, OSAKA UNIVERSITY). TEAM VISITED ABBOTT LABS FACILITIES, JEWISH HOSPITAL IN ST. LOUIS,
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ST. LOUIS RED CROSS CENTER, JOHN ELLIOTT BLOOD BANK, AND

AMERICAN NATIONAL RED CROSS.

5. HAYASHI ALSO SAID REASON FOR GOJ DELAY ON AUSRIA WAS THAT GOJ NEEDED TO DEVELOP A TEST "PANEL" (STANDARD USED TO EVALUATE EFFECTIVENESS OF HEPATITIS TESTS) BUT GOVERN-MENT HOSPITAL WORKERS WERE CONCERNED ABOUT CONTRACTING HEPATITIS WHILE CONSTRUCTING TEST PANEL AND, IT WOULD TAKE ABOUT ONE YEAR TO CONVINCE THEM THAT THEIR SAFETY WOULD

NOT BE JEOPARDIZED. ACCORDING TO FDA, HOWEVER, WORKING WITH HEPATITIS IS NO MORE DANGEROUS THAN WORKING WITH MANY OTHER DISEASES AS LONG AS CERTAIN HEALTH AND SAFETY PRACTICES ARE MAINTAINED. IN FACT, AN FDA LAB TECHNICIAN POINTED OUT THAT THE INCIDENCE OF CONTRACTED HEPATITIS WAS LOWER AMONG LAB TECHNICIANS IN FDA HEPATITIS DIVISIO' THAN IN THE POPULATION-AT-LARGE.

IT MIGHT BE ASKED, IF THE JAPANESE ARE DEVELOPING TEST "PANELS" FOR THE FIRST TIME, ON WHAT BASIS THE CURRENT R-PHA HEPATITIS TEST WAS APPROVED FOR USE BY THE JAPAN RED CROSS, AND WHY AN AMERICAN HEPATITIS TEST MUST PASS A TEST "PANEL" WHEN THE CURRENTLY USED JAPAN RED CROSS HEPATITIS TEST APPARENTLY DID NOT.

6. ABBOTT CLAIMS IT CAN SUPPLY, ON A CONTRACT BASIS, A HEPATITIS TEST PANEL GEARED TO MHW'S SPECIFICATIONS WITHIN TWO OR THREE WEEKS. THEREFORE, MHW'S REPORTED NEED FOR ONE YEAR TO GET A TEST PANEL ESTABLISHED APPEARS TO REPRESENT AH UNREASONABLE DELAY (REF: DAINABOT TO A0BOTT JUNE 13 TELEX FORWARDED TO EMBASSY).

7. IN A MEETING WITH A/S WEIL MAY 30 HANAOKA ALLEGED THAT NO RIA PRODUCTS AVE BEEN APPROVED IN JAPAN SINCE NEW REGULATIONS CONTROLLING RIA PRODUCTS 'ERE ADDED TO THE PAL IN 1974. MOREOVER, HE STATED, TERE IS SOME
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CONCERN OVER THE SAFETY OF RIA TESTS, WHICH EXPLAINS THE DELAY IN AUSRIA'S APPROVAL. ACCORDING TO ABBOTT, HOWEVER, THERE ARE A NUMBER OF RIA TESTS IN USE IN JAPA' TODAY, IMPROVED VERSIONS OF WHICH HAVE BEEN SUBMITTED AND ROUTINELY APPROVED BY MHW SINCE 1974. EXAMPLES INCLUDE THYROID TESTS (E.G. ABBOTT'S T-4, T-3 A'D TSH TESTS), CANCER TESTS, AND DRUG MONITORING TESTS (E.G. DIGOXIN TEST, ALPHA C TO PROTEIN TEST--NEW VERSIONS RECENTLY APPROVED). THE APPROVAL OF THESE OTHER RIA TESTS APPEARS TO CONTRADICT HANAOKA'S ASSERTION THAT ALL RIA TESTS ARE 0EING DENIED APPROVAL PENDING A DETERMINATION OF THEIR SAFETY.

8. USDOC BELIEVES THE TYPES OF ARGUMENTS EMPLOYED BY GOJ

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TO JUSTIFY CONTINUED DELAY IN APPROVING AUSRIA ARE UNACCEPTABLE AND DILATORY. THE EMBASSY MAY WISH TO USE THE INFORMATION SUPPLIED 0Y A0BOTT A'D FDA TO HEAD OFF ANOTHER FORMAL NON-RESPONSE BY M'W ALONG THE LINES SUGGESTED BY HANAOKA AND HAYASHI. ALSO SUGGEST A MEETING BETWEEN EMBASSY, MHW AND ABBOTT REPS MAY BE USEFUL.

9. ACTION REQUESTED: EM0ASSY SHOULD IMPRESS UPON GOJ THE HIGH LEVEL OF USG INTEREST IN THE EXPEDITIOUS AND FAVOR-ABLE RESOLUTION OF THIS CASE AS EVIDENCED IN THE STATE-MENTS OF A/S WEIL (CABLE REPORT OF WEIL/HANAOKA MEETING MAY 31 0EING SENT), UNDER SECRETARY COOPER (REF C), AND A/S STATE KATZ (REF D).

10. NOTE: THIS CABLE PREPARED BEFORE RECEIPT OF TOKYO 11301 (REF E). IT PROVIDES SOME OF INFO REQUESTED IN REF E; MORE DETAILED INFO (TELEXES, ETC) HAS BEEN FOR-WARDED AS NOTED IN TEXT ABOVE. MORE DETAILED REPLY FOCUSSING ON ALL OF EMBASSY'S REQUESTS WILL BE SENT SOON.
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